

AUG 14 2006

5. 510(K) SUMMARY

Applicant: Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: +1-800-729-7272
Fax: +1-909-839-8804

Date: May 25th, 2006

Contact Person: Natalie Bennington
Project Manager, Regulatory Affairs

Proprietary Device Name: ESOPHASTAR™ Esophageal Mapping Catheter

Common Device Name: Electrophysiologic Mapping Catheter

Classification Name: Electrode Recording Catheter
(per 21 CFR 870.1220, Product Code DRF)

Predicate Devices:

- a) Star Diagnostic Catheter (K954390) (later renamed NaviStar Diagnostic Catheter)
- b) ENTRIFLEX Feeding Tube (K833621)

Manufacturer: Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

5.1 Substantially Equivalent To:

The Biosense Webster, Inc. ESOPHASTAR™ Esophageal Mapping Catheter is substantially equivalent to the Biosense Webster NaviStar Diagnostic Catheter (K954390, cleared Dec. 21, 1995) and the ENTRIFLEX Feeding Tube (K833621, cleared Nov. 28, 1983).

5.2 Description of the Device Subject to Premarket Notification:

The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter is a mapping catheter to be used exclusively for anatomically mapping points within the esophagus

using CARTO™ Navigation System technology to indicate the relative anatomical relationship between the esophagus and posterior wall of the left atrium. The EsophaStar is intended to be used in addition to other tools and techniques used to assist the physician in obtaining generalized location information of the esophagus with respect to the heart. The device is introduced through the patient's nose or throat into the esophagus. Once in the desired position, the device's location sensor is used to "map" the 3-D position of the catheter in the esophagus, using Biosense Webster's location software and hardware system, as the device is slowly pulled towards the initial entry port.

The ESOPHASTAR™ Esophageal Mapping Catheter is 8 F in diameter and is 125 cm long. The catheter has a flexible polyurethane shaft with an atraumatic tip section. This catheter has a magnetic location sensor embedded in the tip and, therefore, is used with the CARTO™ EP Navigation System (a magnetic field location technology) and a REFSTAR™ with QWIKPATCH™ External Reference Patch to tag the esophagus.

For further description of the CARTO™ EP Navigation System, refer to the operating instructions for this system.

5.3 Indications for Use:

The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter and related accessory devices are indicated for catheter-based anatomic mapping of the esophagus. When used during an electrophysiology ablation procedure, the EsophaStar is intended to be used in addition to other tools and techniques used to assist the physician in obtaining generalized location information of the esophagus with respect to the heart. The device is not intended to provide absolute esophageal wall location information. The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter is placed in the esophagus via the transpharyngeal or transnasal approach.

5.4 Performance Data:

The ESOPHASTAR™ underwent bench testing and was also tested under simulated use conditions in animals. The Catheter passed all intended criteria in accordance with appropriate test criteria and standards.

5.5 Overall Performance Conclusions:

The nonclinical studies demonstrate that the ESOPHASTAR™ Esophageal Mapping Catheter is safe and effective for anatomic mapping of the esophagus and establish equivalence of the ESOPHASTAR™ Esophageal Mapping Catheter to the predicate devices, the NaviStar Diagnostic Catheter and the ENTRIFLEX Feeding Tube.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2006

Biosense Webster, Inc.
c/o Ms. Natalie Bennington
Project Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K061463
Trade/Device Name: ESOPHASTAR™ Esophageal Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: May 25, 2006
Received: May 26, 2006

Dear Ms. Bennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

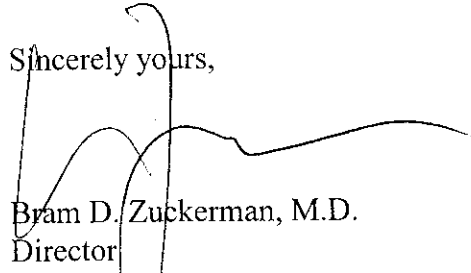
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Ms. Natalie Bennington

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K061463

Device Name: ESOPHASTAR™ Esophageal Mapping Catheter

Indications for Use:

The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter and related accessory devices are indicated for catheter-based anatomic mapping of the esophagus. When used during an electrophysiology ablation procedure, the EsophaStar is intended to be used in addition to other tools and techniques used to assist the physician in obtaining generalized location information of the esophagus with respect to the heart. The device is not intended to provide absolute esophageal wall location information. The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter is placed in the esophagus via the transpharyngeal or transnasal approach.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular

Page 1 of 1

510(k) Number K061463